

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number  
**WO 01/43804 A1**

(51) International Patent Classification<sup>7</sup>: A61M 16/06, A61B 5/08

(21) International Application Number: PCT/IB00/01712

(22) International Filing Date:  
20 November 2000 (20.11.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/465,054 16 December 1999 (16.12.1999) US

(71) Applicant (for all designated States except US): COM-  
PUMEDICS SLEEP PTY. LTD. [AU/AU]; 1 Marine Pa-  
rade, Abbotsford, VIC 3067 (AU).

(72) Inventor; and

(75) Inventor/Applicant (for US only): BURTON, David  
[AU/AU]; 62 Broadway, Camberwell, VIC 3124 (AU).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

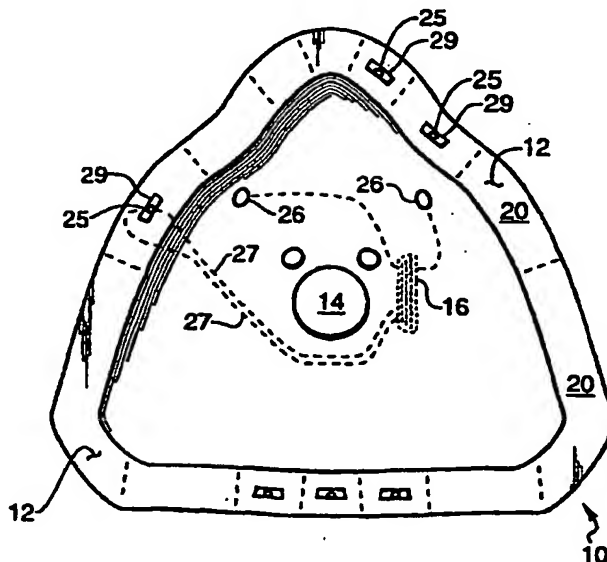
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: BIO-MASK WITH INTEGRAL SENSORS



(57) Abstract: A breathing mask (10) for use in monitoring a patient, providing sensors (25, 26) built into the mask (10) for ease of application to a patient such that donning the mask (10) places all the required sensors on the patient. The mask (10) has a perimeter (12) with a soft pliable material with sensors (25) therein for contacting the patient's skin and making an airtight seal. The mask (10) also has sensors (26) on the body of the mask and on associated straps or caps. The sensors (25, 26) can be used for monitoring the patient's EMG, EEG, EOG, ECG, surface blood pressure, temperature, pulse, blood oxygen, position of the patient, activity level of the patient, sounds and gas pressure in the mask (10).

1  
2 **"Biomask with Integral Sensors"**  
3  
4  
5

6 **Background of the Invention**  
7

8 **Field of the Invention**  
9

10 This invention relates to a breathing mask with built in sensors for monitoring  
11 patients with sleep apnea, breathing disorders for use during anesthesia or ventilation  
12 support.  
13

14 **Description of the Related Art**  
15

16 Masks such as shown in patent 5,243,971 for applying a positive pressure to  
17 patients with apnea and other breathing disorders have been developed. These masks  
18 provide seals for preventing air from escaping from the mask at the junction of the  
19 mask and face. Other types of masks for gas delivery to a patient are also in common  
20 use.

21 Measuring air flows to a patient has been accomplished by metering sensors in  
22 the air supply connected to the mask as in patent 5,503,146 or by belts around the  
23 patients chest to measure his breathing as in patent 5,131,399.

24 Some devices such as in patent 5,507,716 provide sensors combined with  
25 sleep masks for covering the eyes of a patient. However there is no known example of

1 sensors built into breathing masks for monitoring or studying patients with breathing  
2 disorders.

3       Currently if a patient is to be carefully monitored a plurality of electrodes or  
4 sensors would have to be individually applied to the patient and wired to recording  
5 equipment. The plurality of sensors and tangle of ensuing wires impede the usage of  
6 such monitoring equipment. Sensors providing useful information include Electro-  
7 encephalogram (EEG), electromyography (EMG), electro-oculogram (EOG), electro-  
8 cardiogram (ECG), Pulse Transit Time (PTT), gas flow sensors, temperature sensors,  
9 microphones, blood oxygen meters, blood pressure sensors, pulse sensors, patient  
10 movement, position, light, activity sensors, mask leakage, mask pressure, eye  
11 movement by polyvinylidene flouride-(PVD) or Piezo, and other means of gathering  
12 data about the patient or his environment.

13       It is very inconvenient for the patient and the health care worker to attach a  
14 series of different devices to a patient to monitor a plurality of different parameters  
15 simultaneously. Therefore a single device for easily measuring a plurality of  
16 parameters is desired.

17

## 18                               Summary of the Invention

19

20       The invention relates to providing sensors in breathing masks to make it easy  
21 to monitor a patient. The mask has a soft pliable seal material around its perimeter in  
22 contact with the patient's face to form a secure seal therewith. Sensors may be  
23 recessed into the soft pliable seal material at the surface for contact with the skin of  
24 the user when the mask is applied to the user's face. The wiring for the sensors may  
25 be inside the soft pliable seal material insulating the wires from damage during use of

1 the mask. Many sensors can be incorporated into the mask. Sensors may be placed on  
2 the perimeter or on other portions of the mask not in contact with the skin. Sensors  
3 may also be placed on straps or caps used in conjunction with the masks or on other  
4 devices used with the mask.

5 Monitoring of patients with sleep disorders, breathing disorders or for  
6 anesthesia is made easier and more convenient for the patient and for the health care  
7 provider since all the sensors needed are built into a mask which is easily and quickly  
8 placed on the patient with all the wiring to the sensors integral with the mask and  
9 accessed by a single plug.

10 The types of sensors on or in the mask and straps or caps connected to the  
11 mask include but are not limited to oximetry sensors, patient position sensors, eye  
12 movement sensors, leak detection sensors, EEG, EMG, EOG, ECG, PTT,  
13 microphones, pulse, blood pressure, oxygen saturation, temperature, movement  
14 sensors, position sensors, light sensors, leak detection sensors and gas delivery  
15 sensors.

16 Connections to outside sources of gases delivered to the mask are by a gas  
17 nozzle hook up on the mask. A connection to electrical power and data output cables  
18 are by a plug in to a cable connecting to the mask. Alternatively batteries in the mask  
19 and telemetry equipment in the mask can provide power and transmission of the data  
20 to a microprocessor or computer. For portability the microprocessor can be attached  
21 to the mask or be carried by the patient. Similarly a bottle of gas may be connected to  
22 the mask and carried by the patient to allow mobility of the patient while wearing the  
23 mask.

24 Unique applications for the bio-mask include the capability to apply  
25 anesthesia-depth monitoring while administering anesthesia gas to a subject. The

1 ability to monitor the patient non-invasively with the bio-mask while at the same time  
2 administering the anesthesia gas to the patient provides a bio-feedback function for  
3 immediate and responsive anesthesia depth of the subject. The bio-mask can be used  
4 to determine the subject's sleep state by applying standard sleep staging criteria, such  
5 as that of R&K rules and/or the application of diagnostic techniques which analyze a  
6 number of EEG signals, such as Bispectral Analysis. The invention is unique in its  
7 capability to apply such analysis with the minimal-invasive application of a subject  
8 breathing mask.

9 R&K rules refer to "A Manual of Standardized Terminology, Techniques and  
10 Scoring System for Sleep Stages of Human Subject" by Rechtschaffen and Anothony  
11 Kales, Editors 1968 which is hereby made a part hereof and incorporated herein by  
12 reference.

13

14

#### Objects of the Invention

15

16 It is an object of the invention to monitor a patient.

17 It is an object of the invention to provide data needed to help treat a patient.

18 It is an object of the invention to provide sensors for monitoring a patient in or  
19 on a breathing mask or on its associated parts.

20 It is an object of the invention to regulate the flow of gasses to a patient based  
21 on the data obtained from monitoring the patient.

22 It is an object of the invention to diagnose the patient based on data obtained  
23 from monitoring the patient.

24 It is an object of the invention to easily and quickly apply all the sensors  
25 needed for monitoring the patient.

1 Other objects, advantages and novel features of the present invention will  
2 become apparent from the following detailed description of the invention when  
3 considered in conjunction with the accompanying drawing.  
4

#### 5 Brief Description of the Drawings

6

7 Fig. 1 shows a schematic view of the zones for sensors on the inside surface of a soft  
8 pliable material on the perimeter of the breathing mask.

9 Fig. 2 shows a view of the sensors and wiring inside the soft pliable material on the  
10 perimeter of the breathing mask.

11 Fig. 3 shows a side schematic view of the sensors and the wiring inside of the soft  
12 pliable material on the perimeter of the breathing mask.

13 Fig 4 shows a side schematic view of the straps connected to the mask with sensors  
14 embedded in the straps and the mask.

15 Fig. 5 shows a schematic view of the sensor zones on the perimeter of the breathing  
16 mask.

17 Fig. 6 shows a schematic view of the sensors on the inside surface of a breathing  
18 mask.

19 Fig. 7 shows a side schematic view of the mask with sensors on the surface of the  
20 mask.

#### 21 Description of the Preferred Embodiments

22

23  
24 Fig. 1 shows the inside of mask 10 including the perimeter surface 12 which  
25 contacts the patient's face. The perimeter surface 12 has a plurality of zones 20. Each

1 zone 20 having a sensor 25 in a recess 29 for measuring a parameter of the patient to  
2 be monitored or other data such as gas leakage. Other sensors 26 are on the mask 10  
3 but not in contact with the patient's skin. These sensors 26 measure patient data or  
4 related data such as ambient light, gas pressure in the mask or ambient temperature.  
5 The mask 10 has a gas connector 14 for connecting a hose 32 to provide a gas to the  
6 mask 10 and a mask interface connector 16 for plugging in a cable 30 for a power  
7 supply and for data transmission.

8 In some embodiments of the invention the sensors 25 do not require an outside  
9 source of power as the sensors such as heat sensors and light sensors generate current.

10 The mask perimeter surface 12 is preferably made out of a soft pliable  
11 material such as silicone rubber for making a good sealing contact with the face of the  
12 patient to prevent gas leakage. The material should be soft and pliable enough to  
13 follow the contours of the face. The perimeter surface preferably has recesses 29 on  
14 the surface for the insertion of sensors 25 so that the sensors can make contact with  
15 the patient's skin when the mask is pressed against the patient's face.

16 As seen in Fig. 3 a sensor or electrode 25 attachment to the mask 10 preferably  
17 utilizes a rubber compound 28 such as silicon or other food grade type rubber  
18 embedded with carbon or other conductive materials for electrical contact of skin to  
19 the mask. As shown in Fig. 2 the recesses 29 are large enough to have room to make  
20 electrical connections to leads 27, which are buried in the soft pliable material under  
21 the perimeter surface 12. The leads 27 are thus protected from damage and electrically  
22 insulated. Preferably the sensors 25 will plug into the leads 27 or printed circuits in  
23 the recesses 29. The leads 27 are preferably on printed circuits embedded in the mask  
24 or fine wires embedded in the mask and connect the sensors 25 to the mask interface  
25 connector 16.

1        Fig. 5 shows conductive material 40 on the surface in zones 20, such as carbon  
2        embedded silicon, can be used on the surface of the perimeter 12 of mask 10 in  
3        separate zones 20 to conduct the electrical surface energy from the patient's face. The  
4        conductive material 40 is preferably moisture activated to improve the its electrical  
5        conductivity when in contact with the skin. The conductive material 40 may be  
6        applied for all electrode 25 contacts in all zones 20. Alternatively electrodes 25 may  
7        directly contact the patients face. The electrodes may also be inside of the soft pliable  
8        material on the perimeter 12 of the mask 10.

9        Fig. 4 shows a side view of the mask 10 and straps 35 used to keep the mask  
10       in place on a patient. The straps 35 have sensors 25 connected to leads 27, which  
11       connect the sensors to the mask interface connector 16 and to cable 30 for  
12       transmitting data to a computer or other device. The sensors 25 in the straps 35 may  
13       be electro-encephalogram EEG sensors for measuring brain waves. The straps 35 may  
14       be replaced with a cap having sensors therein. Alternatively a chin strap 37 may be  
15       used having sensors 25.

16       Fig. 5 shows an example of the types of sensors 25 used in zones 20 around  
17       the perimeter of the mask 10. Physiological signals from a patient's skin potential are  
18       detected by sensors in the zones 20 around perimeter 12 of mask 10. Conductive  
19       electrode paste 40 may be used to improve the electrical contact between the sensors  
20       25 and the surface of the skin. The conductive paste 40 can assist in reducing the  
21       impedance between the face and the electrical output from the sensors 25 in zones 20.  
22       The conductive paste 40 may also assist in preventing gas leaks.

23       As an example of a mask sensor layout the following sensors and their  
24       functions are described. However many other types of sensors and arrangements of  
25       the sensors are possible.



1           Zone 50 is an electro-oculogram (EOG) to obtain electrical eye movement  
2 reference signals from over the bridge of the nose.

3           Zone 51 is an EOG to detect electrical eye movement signals for the inner left  
4 eye and zone 61 is designated for electrical eye movement signals for the inner right  
5 eye. Eye movement data is related to stages of sleep such as rapid eye movement  
6 REM, which indicates a deep sleep state and dreaming.

7           Zone 52 is designated for an EOG to detect electrical eye movement signals  
8 for the outer left eye and zone 62 is designated for electrical eye movement signals for  
9 the outer right eye.

10          Zone 53 is designated for electro-myography (EMG) to detect electrical  
11 signals from muscle contractions in the upper left chin. Zone 63 is correspondingly  
12 for the upper right chin. Zones 54 and 64 are for the lower left and lower right chin  
13 respectively. The amplitude of the chin signals is proportional to the relaxation state  
14 and subsequent sleep state of the patient.

15          Zone 55 is the EMG for the upper left lip, giving information about sleep  
16 stages. It is proportional to the relaxation and sleep states of the patient. Zone 65 is the  
17 EMG for the upper right lip.

18          Zone 56 is the EMG for the left nasal inner mask it also provides signals for  
19 the lip movements and is proportional to the relaxation and sleep states of the patient.  
20 Similarly zone 66 is for the right nasal inner mask EMG:

21          Zones 57 and 67 are for the oral left and oral right outer mask EMG signals  
22 which are also proportional to the relaxation and sleep states of the patient.

23          Zone 70 is for pressure sensor ports for airflow determination.

24          Microphone 80 on the mask detects the patients breathing or snoring sounds.

1        Fig. 6 shows an alternate embodiment where two sensors 58 and 68 are used  
2        to find the patient's electrocardiogram ECG. This data is also useful for monitoring a  
3        patient. The patient's heart functions provide a lot of useful data about the patient's  
4        condition. Pulse Transit Time (PTT) is the time it takes ECG pulses to travel from the  
5        heart to a sensor such as a sensor placed on the head, on a finger tip, or on the ear.  
6        PTT sensors can be in the mask, on sensors connected to the mask, or sensors used in  
7        conjunction with the mask. PTT measurements are used to determine patient arousals  
8        and qualitative blood pressure variation.

9        Thermal sensor 81 is used on the inside surface of the mask to detect nasal  
10       breathing. Thermal sensor 82 is used on the outside surface of the mask to detect oral  
11       breathing. The thermal sensitivity of the sensors 81 and 82 on the surface of the mask  
12       10 opposite the nose or mouth indicates if the patient is breathing through his nose or  
13       mouth. The thermal sensors 81, 82 may alternatively be placed on the inside of the  
14       mask 10, on the outside of the mask 10, or inside of the material of mask 10 for  
15       detecting breathing. The thermal sensors 81, 82 may be a thermistor material, a  
16       thermocouple material or any other temperature sensitive material. The thermal  
17       sensors 81, 82 may be coatings on the inside of the mask, the outside of the mask or in  
18       the mask. The thermal sensors 81, 82 detect heat, which is proportional to the amount  
19       of breathing.

20       It is important to detect oral breathing for undetected or partially undetected  
21       oral breathing effects the integrity of the patient breathing gas breath monitoring and  
22       subsequently compromises the idea gas delivery to the patient. It is important to detect  
23       mouth breathing to assist in diagnosis of sleep disordered breathing. Further, control  
24       of a mask nasal ventilation is effected by mouth breathing.

1 A pressure sensor 84 measures the pressure inside of the mask to indicate if  
2 there is positive pressure inside of the mask and how much. A pressure drop may  
3 indicate a leak.

4 A surface reflective oximetry sensor 85 on the inside of the mask detects the  
5 patients pulse rate and oxygen saturation.

6 A surface blood pressure sensor 90 on the perimeter 12 of the mask 10 in  
7 contact with the patient can be used to monitor the patients blood pressure.

8 A thermistor 91 on the perimeter 12 of the mask 10 in contact with the patient  
9 can be used to monitor the patients temperature.

10 A patient recycled air detection system having a sensor 95 on the inside  
11 surface of the mask detects the amount expired air from the patient remaining in the  
12 mask 10. High levels of expired gas in the mask indicates the mask is not being  
13 flushed out and may lead to problems if not enough fresh gas is introduced.

14 A patient back gas occurrence detector 97 in the mask hose connector 14  
15 detects the amount of expired gas in the mask returning with newly delivered gas.

16 Fig. 7 shows thermal sensors 83 such as thermistors or thermocouples on the  
17 inside or outside of the mask adjacent the perimeter 12. These sensors can be attached  
18 to a thermally conductive material 92 around the perimeter of the mask 10.

19 Alternatively the thermally conductive material may be on portions of the perimeter.  
20 This thermally sensitive material can be on the inside surface of mask 10, the outside  
21 surface of mask 10 or embedded within the mask material. Detection of a temperature  
22 change by thermal sensors 83 or thermal sensors 83 on thermally conductive material  
23 92 correlates with mask leakage around the perimeter. The thermally sensitive  
24 material may be a thermally sensitive material in the mask on the inside of the mask,  
25 on the outside of the mask or on the perimeter of the mask. The thermally sensitive

1 material may be a thermistor, a thermocouple, or any other thermally sensitive  
2 material.

3 Gases leaking from the mask 10 will cause a temperature change associated  
4 with the thermally conductive material 92 and sensors 83 and allow a healthcare  
5 specialist real-time monitoring of leak status or post monitoring status of mask  
6 leakage. In some instances this can be life saving where a patient's gas delivery is  
7 critical and in other cases the leakage incidence can assist in the diagnosis of a patient.

8 This assistance may be in the form of alerting a health care specialist that the gas  
9 delivery was subject to leakage and this may affect patient treatment and patient  
10 diagnostic conditions. In other instances the gas leakage detection can allow the gas  
11 delivery system to automatically compensate for the gas leakage.

12 A light sensitive resistor 86 on the outside surface of the mask 10 indicates the  
13 ambient lighting conditions of the patient.

14 Position sensors 87 indicate position or activity of the patient. For example  
15 these sensors show if the patient is lying down and is motionless. Such a sensor may  
16 be a moving ball across switch contacts, or mercury sensor switches.

17 Body movement sensor 88 can be a PVD or piezo material or micro  
18 mechanical to detect the patients body movements extent and rate to determine a  
19 wake versus rest state.

20 All of the above sensors may send data by telemetry rather than by cable 30.

21 All of the above collected data may be used to monitor a patient for a variety  
22 of uses including sleep studies, anesthesia and sleep apnea.

23 The data collected can be converted to a serial data stream to allow a single  
24 wire to interface all the sensors. The sensors may provide data to adjust gas delivery  
25 to the patient.

1 Gain and filtering adjustments to the signals may be used to condition the  
2 signals close to source for optimal noise and signal performance.

3 An electrical bias to sensors such as a patient position sensors, thermal  
4 conductive zones, microphones, or light dependent resistor may be applied.

5 A computer may process the data or simply store the data to from the  
6 monitoring sensors in the mask or straps attached thereto. The monitoring data may be  
7 used to diagnose a patient, provide feedback to machines attached to the patient,  
8 increase or decrease air supplies to a patient or perform other functions.

9 An example of EEG data controlling in a bio-feedback application the delivery  
10 of gas to a patient may be when a patient has a nasal ventilation device such as a  
11 ventilator Continuous Positive Air Pressure (CPAP), Bi-Positive Air Pressure  
12 (BIPAP), Variable Positive Air Pressure (VPAP), Sleep Linked Positive Air Pressure  
13 (SPAP) and the EEG electrodes provide one of the vital signs of if the patient is  
14 asleep. Gas is only applied to the mask when the patient is deemed to be asleep. This  
15 function is more sophisticated, sensitive to patient comfort and commercially viable  
16 than delay ramp systems used on some ventilation systems.

17 In ventilation devices that use delay ramps the user sets a time of the system  
18 allocates a time and ramps up the gas pressure delivery to the patient so that the  
19 application of gas does not have as much disturbing affect on the user and adversely  
20 effect his ability to sleep.

21 The sensors in the mask 10 are better able to determine when the patient is  
22 actually asleep before applying assisted nasal ventilation. Premature application of  
23 pressure can prevent the patient from sleeping due to the added discomfort of positive  
24 pressure.

1       The mask 10 may be made such that it is a sterile disposable unit for medical  
2 use thus lowering costs of treatment by not needing to sterilize masks for new patients  
3 and providing a more sterile treatment than reusable masks.

4       Obviously , many modifications and variations of the present invention are  
5 possible in light of the above teachings. It is therefore to be understood that, within  
6 the scope of the appended claims, the invention may be practiced otherwise than as  
7 specifically described.

8       What is claimed is:

1

1 1. A mask with sensors for monitoring a patient during gas delivery comprising:  
2 a mask having a perimeter for contacting the face of a patient,  
3 at least one sensor on the mask to sense at least one parameter indicating a  
4 state of the patient,  
5 leads in the mask connected to the at least one sensor for transmission of data,  
6 a means for transmitting data from the mask,  
7 a hose connector on the mask for attachment of a hose for delivery of gas to  
8 the mask.

1  
1 2. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 the means for transmitting data from the mask comprises a mask interface  
4 connector for connecting the leads in the mask to a cable.

1  
1 3. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 comprising,  
3 a means for providing power to the mask to operate the sensors.

1  
1 4. A mask with sensors for monitoring a patient during gas delivery as in claim 3  
2 wherein,  
3 the means for providing power to the mask to operate the sensors comprises a  
4 mask interface connector connecting a power source lead to a lead in the mask for  
5 transmitting power to a sensor and;  
6 the means for transmitting data from the mask comprises a mask interface  
7 connector for connecting the leads in the mask to a cable.

1 5. A mask with sensors for monitoring a patient during gas delivery as in claim 3  
2 wherein,  
3 the means for providing power to the mask to operate the sensors comprises a  
4 battery attached to the lead in the mask for transmitting power to a sensor and;  
5 the means for transmitting data from the mask comprises a telemetry device.  
1

1 6. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 the sensors on the mask are selected from the group consisting of, EEG, EMG,  
4 EOG, ECG, PTT, temperature, surface blood pressure, pulse, blood oxygen level,  
5 light, breathing rate, breathing volume, gas flow, nasal air flow, oral air flow,  
6 position, activity sensors, mask leakage, mask pressure, eye movement, microphones,  
7 gas pressure, patient recycled air detection, patient back gas and movement.  
1

1 7. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 at least one sensor on the perimeter of the mask makes contact with the skin of  
4 the patient for measuring a parameter.  
1

1 8. A mask with sensors for monitoring a patient during gas delivery as in claim 7  
2 wherein,  
3 the perimeter of the mask has a soft pliable material for contacting the face of  
4 the patient.  
1



1 9. A mask with sensors for monitoring a patient during gas delivery as in claim 8  
2 wherein,

3 the material has at least one recess with a sensor in the recesses for contacting  
4 the skin of the patient.

1  
1 10. A mask with sensors for monitoring a patient during gas delivery as in claim 9  
2 wherein,

3 leads in the pliable material are connected to the at least one sensor for power  
4 and data connections therewith.

1  
1 11. A mask with sensors for monitoring a patient during gas delivery as in claim 8  
2 wherein,

3 a carbon embedded rubber material provides electrical contact between the  
4 sensor in the soft pliable material and the patient's skin.

1  
1  
1 12. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,

3 the mask has at least one strap attached to the mask to hold the mask in place.

1  
1 13. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,

3 the mask has at least one strap attached to the mask to hold the mask in place  
4 and the strap has at least one sensor wired to the mask for monitoring the patient.

1

1 14. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 the mask has a cap attached to the mask to hold the mask in place.

1 15. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 the mask has a cap with at least one sensor attached to the cap, the sensor  
4 leads on the cap connected to the leads in the mask for monitoring the patient.

1 16. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 13 wherein,  
3 the strap includes a chin strap.

1 17. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 at least one sensor in the chin strap for measuring chin EMG

1 18. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 13 wherein,  
3 the straps include a head strap having a sensor for measuring EEG.

1 19. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 15 wherein,  
3 the cap includes sensor for measuring EEG.

1 20. A mask with sensors for monitoring a patient during gas delivery as in claim

2 13 wherein,

3 the strap includes an ear strap having an oxygen saturation sensor applied to  
4 the ear of the patient.

1

1 21. A mask with sensors for monitoring a patient during gas delivery as in claim 1

2 wherein,

3 a thermal sensor on a portion of the mask detects changes in temperature on  
4 that portion of the mask.

1

1 22. A mask with sensors for monitoring a patient during gas delivery as in claim

2 21 wherein,

3 the mask has a thermally conductive material to which the thermal sensors are  
4 thermally coupled.

1

1 23. A mask with sensors for monitoring a patient during gas delivery as in claim 1

2 wherein,

3 a thermally sensitive material on the mask proximate the patient's nose detects  
4 temperature variations for nasal breathing detection.

1

1 24. A mask with sensors for monitoring a patient during gas delivery as in claim 1

2 wherein,

3 a thermally sensitive material on the mask proximate the patient's mouth  
4 detects temperature variations for oral breathing detection.

1

1 25. A mask with sensors for monitoring a patient during gas delivery as in claim 1  
2 wherein,  
3 a thermally sensitive material on the mask proximate mask perimeter detects  
4 temperature variations for leak detection.

1 26. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 21 wherein,  
3 the thermally sensitive material comprises a thermistor.

1 27. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 21 wherein,  
3 the thermally sensitive material comprises a thermocouple.

1 28. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 21 wherein,  
3 the thermally sensitive material comprises a coating on the mask.

1 29. A mask with sensors for monitoring a patient during gas delivery as in claim  
2 21 wherein,  
3 the thermally sensitive material portion of the mask comprises an internal  
4 surface portion of the mask.

1.

1 30. A mask with sensors for monitoring a patient during gas delivery as in claim

2 21 wherein,

3 the thermally sensitive material portion of the mask comprises an external

4 surface portion of the mask.

1

1 31. A mask with sensors for monitoring a patient during gas delivery as in claim

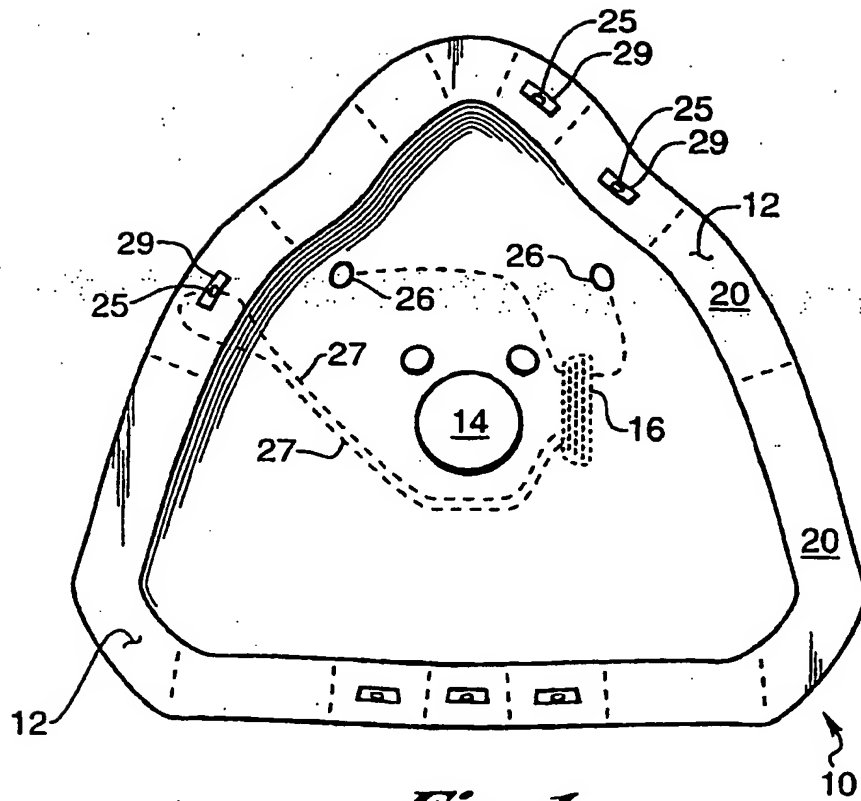
2 21 wherein,

3 the thermally sensitive material portion of the mask comprises a portion within

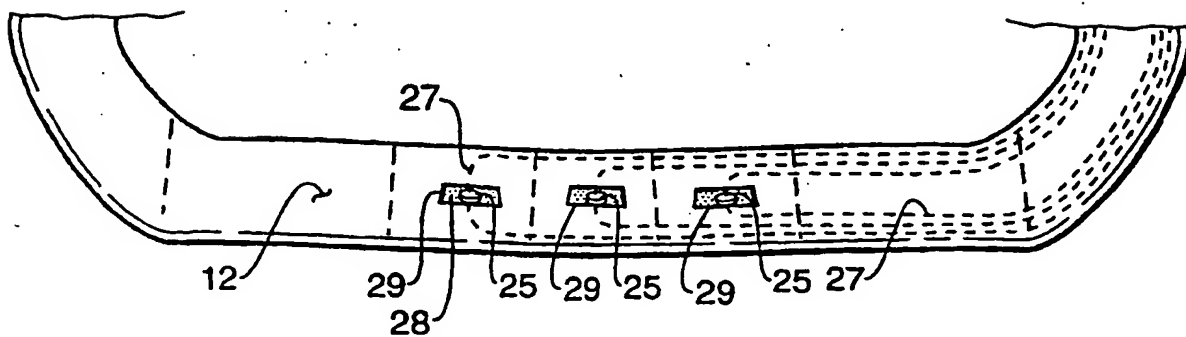
4 the mask material.

1

1/4

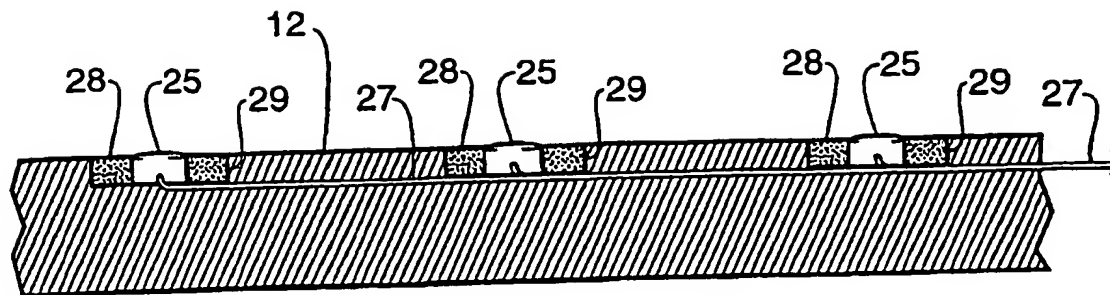
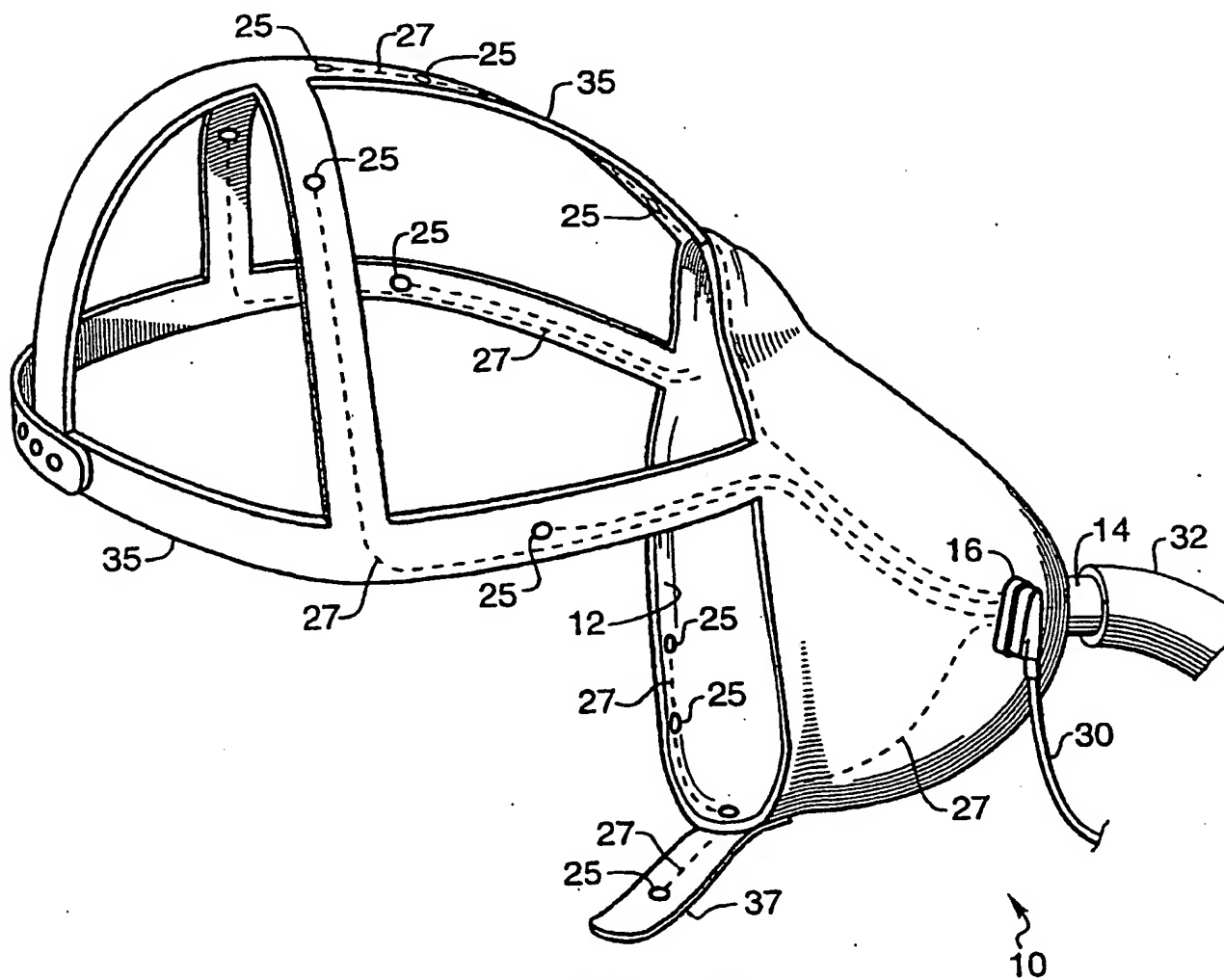


*Fig. 1*

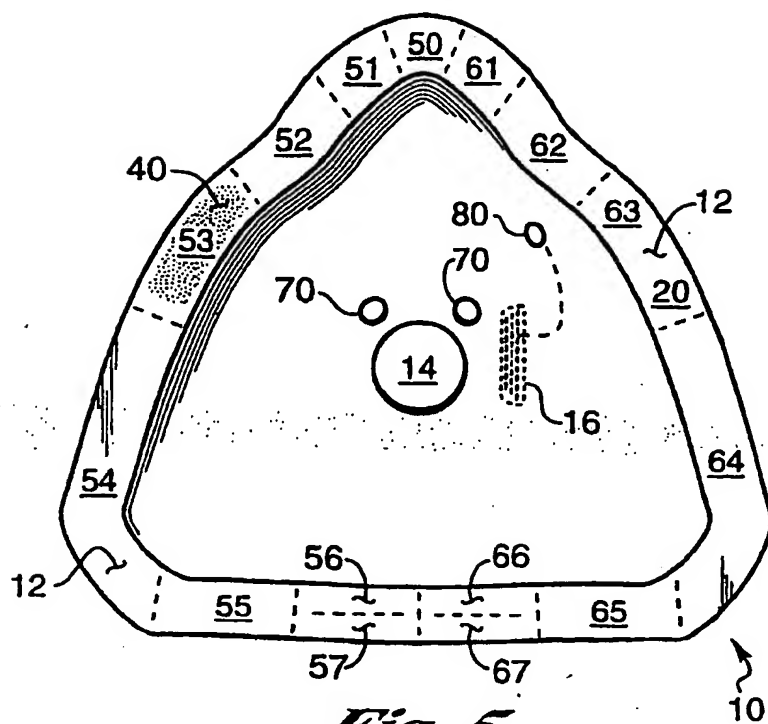


*Fig. 2*

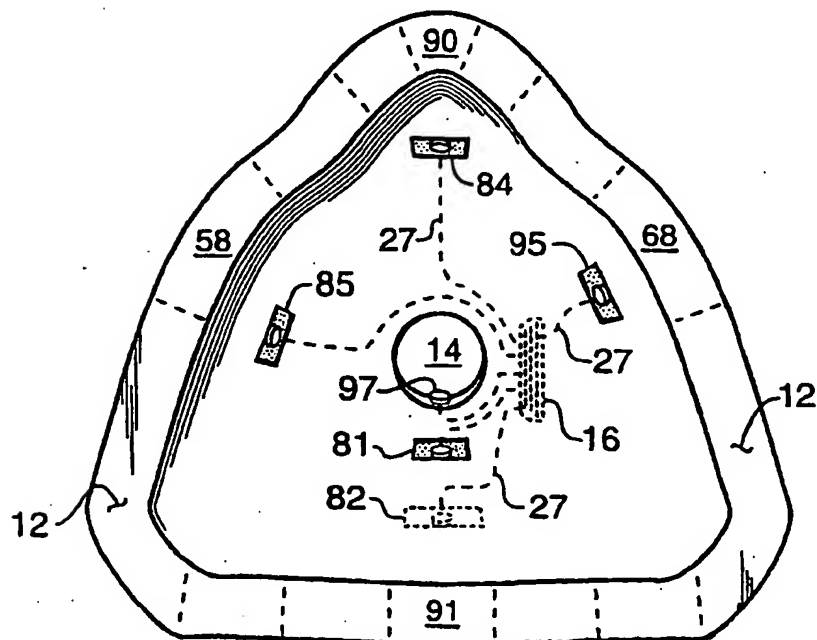
2/4

*Fig. 3**Fig. 4*

3/4



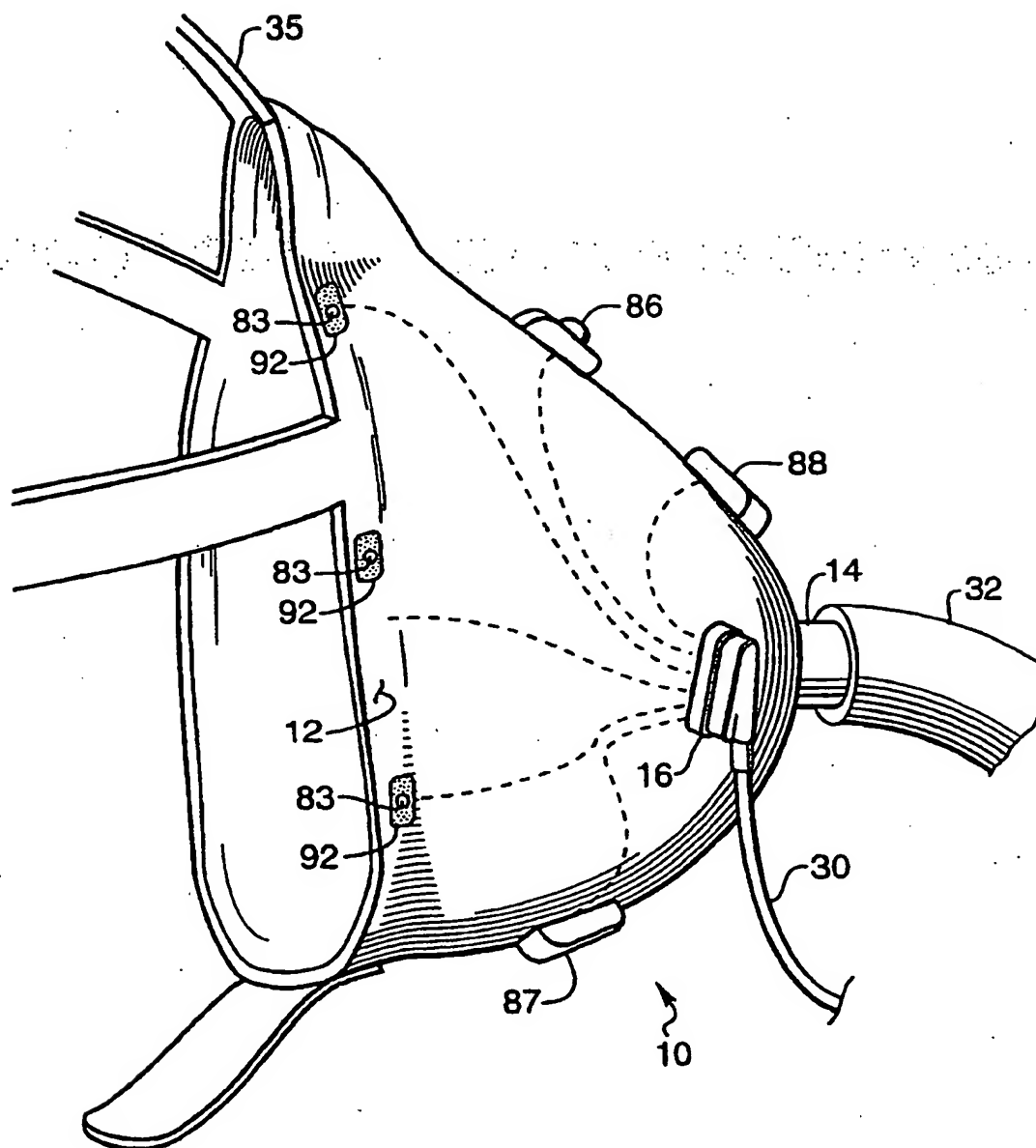
*Fig. 5*



*Fig. 6*



4/4

*Fig. 7*

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB00/01712

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int. Cl. <sup>7</sup> : A61M 16/06, A61B 5/08		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
Key word search		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
DWPI mask, breath, respir., gas, oxygen, air, anaesthe., apnea, CPAP, sensor, detect, transduc., microphone, integral		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5860417 A (Kettl et al) 19 January 1999 Column 5, line 23 to Column 10, line 60 and Figures 1 to 6	1 to 6, 12
X	WO 97/33641 A (Beth Israel Deaconess Medical Centre, Inc) 18 September 1997 Whole document	1 to 6, 12
X	GB 2294642 A (Brain) 8 May 1996 Whole document	1, 6
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 February 2001		Date of mailing of the international search report 6 March 2001
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  COLIN FITZGIBBON Telephone No : (02) 6283 2226

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB00/01712

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4875477 A (Waschke et al) 24 October 1989 Column 2, lines 45 to line 64	1, 6 to 8, 12

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
**PCT/IB00/01712**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	5860417	US	5503141		
WO	97/33641	AU	20674/97	US	5857460
GB	2294642	CA	2162013	US	5584290
US	4875477	DE	3724336	EP	303056
				JP	1049535
END OF ANNEX					